

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Eric T. Fossel
Application No.: 10/590,300
Confirmation No.: 7179
Filed: June 21, 2007
For: TOPICAL DELIVERY OF A NITRIC OXIDE DONOR TO
IMPROVE BODY AND SKIN APPEARANCE
Examiner: I. Y. Treyger
Art Unit: 3761

DECLARATION UNDER 37 C.F.R. § 1.132

I, Eric Thor Fossel, declare that:

1. I am currently President and CEO of Strategic Science & Technologies, LLC. Before leaving to found Strategic Science & Technologies, LLC in 1994, I was employed by Harvard Medical School as a professor since 1976.
2. I am the inventor of U.S. Pat. Apl. Ser. No. 10/590,300. I have read and understood the specification of this application, the claims as pending, the most recent Final Office Action dated May 9, 2011 (the "Office Action"), the references cited therein, and the enclosed amendment.
3. I have a financial interest in the issuance of this application as a patent. This application is owned by Strategic Science & Technologies, LLC, of which I am the President and CEO, as well as being a stockholder.
4. This declaration is to establish that the presently claimed invention is not obvious over the combination of Fossel, U.S. Pat. Apl. Pub. No. 2003/0028169 ("Fossel") in view of Falk, *et al.*, U.S. Pat. No. 5,824,658 ("Falk"), as is stated in the Office Action.
5. The Patent Office has rejected claims 3, 4, 7-10, 12, 14, 15, 19-23, and 27-29 under 35 U.S.C. § 103(a) on the basis that because each of Fossel and Falk teaches rubbing a delivery vehicle into the skin, and "Since the skin covering the human breast has substantially the same anatomical and morphological structure as other parts of the skin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Fossel the step of rubbing a cream into the skin, as taught by Falk in order to improve therapeutic effect to the treatment (Falk, col. 12, line 16) and increase absorption of the cream caused by increasing the friction that in its turn increases the area of contact of cream with the skin, and thus improves absorption and penetration" (Office Action, section 13, last paragraph on page 4, extending onto page 5).

6. The Office Action does not identify a location in Fossel that teaches rubbing a delivery vehicle into the breast of a subject. The Office Action states that Fossel discloses a method comprising an act of applying a base cream to the selected area of skin in paragraph [0015] of Fossel. The Office Action also states that such a cream is "fully capable" of being applied to the breast, since the skin covering the breast is a selected area of the skin (Office Action, section 13, page 4, first paragraph).
7. Fossel teaches that the composition is useful for wound healing, increasing erectile function, and increasing growth of hair (Abstract). Fossel also teaches that the composition is useful for healing of leg ulcers secondary to diabetes or confinement to bed (paragraph 0003) or other superficial ulcers of the limbs (paragraph 0008). The examples describe hair growth (Example 1) and treatment of impotence (Examples 2 and 3). However, treatment of a breast is not disclosed.
8. None of these rationales is relevant to applying the compositions of Fossel to the breast. The breast is not an area of the skin where hair growth is desired. Indeed, the breast is not an area of the skin where substantial hair growth is generally seen. Nor is the breast an area prone to ulcers as is described in Fossel. Nor is the treatment of erectile dysfunction in males relevant to treatment of the breast.
9. The Office Action also does not identify a location in Falk that teaches rubbing a delivery vehicle into the breast of a subject. The Office Action states that Falk teaches a method of treating the skin by rubbing a gel or cream into the skin in Col. 12, lines 12-15 (see Office Action, section 13, last paragraph). The Office Action then states that Falk teaches rubbing a cream into the skin would improve its therapeutic effect, identifying Col. 12, line 16 of Falk (Office Action, section 13, last paragraph).
10. Falk teaches treating pain by administering topically to the skin or exposed tissue of a human, a dosage amount of a pharmaceutical composition comprising an NSAID and a hyaluronic acid (Abstract). The passage within Falk identified in the Office Action is taken from a single sentence starting on col. 11, line 62 and extending to col. 12, line 36. Although this sentence recites treatment of metastatic cancer from the breast to the skin, it does not teach or suggest applying a composition to the breast. Instead, this passage recites treatment of the skin or exposed tissue.
11. In contrast, the present invention teaches rubbing a delivery vehicle into the breasts, for example, to cause the breasts to appear fuller and/or raised. This contrasts with Fossel and Falk, neither of which even describes applying a delivery vehicle to the breasts or the resulting change in appearance of the breasts.
12. There are several secondary considerations that also should be considered in evaluating the combination of Fossel and Falk. Some important secondary considerations are commercial success, and evidence of copying.
13. The present invention is embodied within a product currently being sold commercially by Strategic Science & Technologies, LLC as Breast Lift™. This product has been advertised in print

and on the Internet via several distribution channels, including CVS via www.cvs.com, Target via www.target.com, and AmeriMark via www.amerimark.com. See Appendix A, showing web pages where this product is sold (each last accessed February 15, 2012).

14. Breast Lift™ has been commercially successful. For example, over 3,000 units were sold in each of 2008, 2009, 2010, and 2011.

15. Strategic Science & Technologies, LLC also sells other products, including Hair Grow™ (a treatment for hair growth) and Arousal™ (a male enhancement cream, e.g., for erectile dysfunction). These products embody formulations described in the Fossel reference cited in the Office Action.

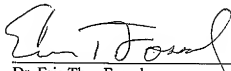
16. Sales for Hair Grow™ and Arousal™ have also been significant. For example, in 2011, sales included over 2,500 units of Hair Grow™ and over 800 units of Arousal™. These products are not the same as Breast Lift™, and each product has exhibited robust sales.

17. There has also been commercial interest from other companies wishing to copy the invention. Significantly, Strategic Science & Technologies, LLC, the assignee of the present invention, has been in negotiations and has recently licensed rights in the invention to FSL Performance Group, LLC, as of January 1, 2012.

18. Accordingly, secondary considerations such as commercial success and evidence of copying should also be considered in evaluating the combination of Fossel and Falk.

19. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like made in a Declaration are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

April 5, 2012
Date


Dr. Eric Thor Fossel
President & CEO
Strategic Science & Technologies, LLC
58 Charles Street
Cambridge MA 02141

APPENDIX A



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Transdermal BreastLift Natural Breast Enhancement Cream

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 \$34.99

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All natural. Helps lift. Improves firmness. Works in one hour. Formulated with L-Arginine, BreastLift Cream offers a safe and natural way to help firm and lift breast tissue. Preliminary testing on women with A, B or C cup sizes show a noticeable increase in firmness within one hour. According to those tested, the effect lasts from several hours up to twelve hours.

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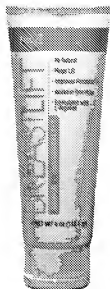
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item details.

- **Used For:** Firming
- **For Use On:** Chest
- **Product Form:** Cream
- **Capacity (volume):** 4.0 Cu. Ft.
- **Power Source:** Manual
- **Scent:** Unscented
- **Travel Size:** Yes

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- **Return Method:** This item can be returned to any Target store or Target.com.
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- **Estimated Ship Dimensions:** 6.2 inches length x 0.3 inches width x 0.6 inches height
- **Estimated Ship Weight:** 0.25 pound

other info.

- **Online Item #:** 10952295
- **Store Item Number (DPCI):** 242-09-2940
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Montmy Nov 17, 2010

Overall

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easy to use effective value

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Sord face Oct 28, 2010

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This cream has really bad smell n it just didn't work For me n it was so heavy

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mizelle Q221 Aug 31, 2009

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Dawn - Part 1 -
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Icronic Puppy GiftCard
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(66)**\$29.99**
Breaking Dawn -
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